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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/050,991	03/31/98	GETZENBERG	R 76333/150

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WASHINGTON DC 20007-8696

EXAMINER

EPPS, J

ART UNIT	PAPER NUMBER
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1635

13

DATE MAILED:

07/06/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/050,991**

Applicant(s)

**Getzenberg**

Examiner

**Janet Epps**

Group Art Unit

**1635**



☒ Responsive to communication(s) filed on Apr 3, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-47 is/are pending in the applicat

Of the above, claim(s) 4-15, 18-20, 22-39, and 44-47 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-3, 16, 17, 21, and 40-43 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 4/08/2000 have been fully considered but they are not persuasive. In reference to the rejection of claims 1, 3, 16-17, 21, and 40-43 under 35 USC 102(b) as anticipated by Coffey et al., and the rejection of claims 1-2, 16-17, and 21 under 35 USC 102(b) as anticipated by Miyanaga et al., applicants have amended the claims to recited "wherein said nuclear matrix protein is specific to renal cells". However, Applicants have not demonstrated that the claimed proteins are specific to renal cells. Absent evidence to the contrary Applicant's claimed proteins may be expressed in other cell types as well.

2. Claims 1-47 are currently pending. Claims 4-15, 18-20, 22-23, 27-31, 34-39, 44-47, 24-29, and 32-34, are withdrawn from further consideration by the examiner as being drawn to a non-elected invention.

### ***Rejections remaining from the prior Office Action:***

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 16-17, 21, and 40-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffey et al. (PTO-1449).

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Coffey et al. disclose nuclear matrix proteins (NMPs) which are characterized by a defined expression in tissue. These NMPs are useful in diagnosing and monitoring the stage of malignancy of a cell and treating cell proliferative disorders. Specifically, Coffey et al. disclose, PC-1 (MW 56 kD), an NMP that is seen in human prostate cancer tissue, malignant kidney and bladder cancer specimens, but not detected in normal prostate, kidney, or bladder tissue. (p. 47, lines 20-25). The method of diagnosing the stage of malignancy of a cell can be accomplished by using antibodies targeting the NMP, or a nucleic acid probe (p. 53, all). In addition, Coffey et al. teach methods of identifying factors which would potentially modify the activity of an NMP, for example monoclonal antibodies and antisense nucleic acids (p. 36).

Coffey et al. teach each and every aspect of the instant invention thereby anticipating applicant's claimed invention.

5. Claims 1-2, 16-17, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Miyanaaga et al.

Miyanaaga et al. disclose a Nuclear Matrix Protein (NMP) that is a 100 kD protein that is released in soluble form from cells undergoing cell death. This protein was used as a urine marker for transitional cell carcinoma. Miyanaaga et al. further teach that their disclosed NMP of 100kD maybe useful in the screening of bladder cancer patients, and for continuous follow-up screening after surgery (p. 457, abstract).

Miyanaaga et al. teach each and every aspect of the instant invention thereby anticipating applicants' claimed invention.

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*New Grounds of rejection Not necessitated by Applicant's Amendment:*

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3, 16, 17, 21, and 40-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention reads on a broad genus of nuclear matrix proteins and methods of using said proteins, wherein said proteins are present in normal renal cells but absent in cancerous renal cells, or conversely are present in cancerous renal cells and absent in normal renal cells. The specification as filed does not provide sufficient description regarding the common structural features of this claimed genus of proteins. The specification clearly fails to describe a representative number of species to allow one skilled in the art to envisage the structures of all members of the claimed genus. Since there is no common structural feature of the claimed nuclear matrix proteins recited in the claim, the scope of the claims include numerous structural variants, the genus of the claims is also highly variant because a significant number of structural differences between genus members are permitted. The general knowledge and level of skill in the art do not supplement the omitted description, because specific not general guidance is needed.

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The specification as filed exemplifies six different nuclear matrix proteins which are associated with specific expression in either normal kidney tissue or in malignant kidney tissue. However, there is no common structural features which distinguish these nuclear matrix proteins from other proteins of the same class or that are predictive of the structure of other members of the same class of proteins.

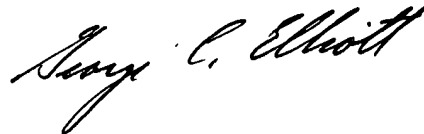
One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the claimed genus of nuclear matrix proteins or methods of using them.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps whose telephone number is (703) 308-8883. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax number for this group is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "George C. Elliott".

George C. Elliott, Ph.D.  
Supervisory Patent Examiner  
Technology Center 1600

Janet L. Epps, Ph.D.

July 2, 2000